Reporting Requirements of ISO Guide 25 and the Prospective Replacement ISO/DIS 17025

Patrick Kershaw
Fluke Corporation
Everett, Washington

Abstract

ISO Guide 25, *General Requirements for the Competence of Testing and Calibration Laboratories*, has been a defining standard in the calibration industry. Prospective standard ISO/DIS 17025 is currently under review to become the replacement for Guide 25. In order to validate the routines used in transfer of measurement between instruments, transfer standards and prime standards, the guide establishes reporting criteria for laboratories providing calibration verification and adjustment. This paper compiles a compact list of those reports required by the guide and provides a cross-reference which may prove useful as laboratories transition to the superceding document. Draft ISO/DIS 17025 identified CS981040033 was referenced during the writing of this paper.

Introduction

The primary purpose of this paper is to compile a compact list of the reporting and documentation requirements of ISO Guide 25, *General Requirements for the Competence of Testing and Calibration Laboratories*, into an easy to use reference, which does not add any requirements by interpretation.

As ISO Guide 25 is in the process of being replaced by ISO/DIS 17025, this paper will offer a cross-reference to the current draft of that document. Where it is possible, there is also cross-reference to ANSI/NCSL Z540, a competency standard commonly used in conjunction with ISO Guide 25 in the United States.

The reporting requirements of ISO Guide 25 can be divided into four groups based on the frequency and routine of the report requirement.

The first group, referred to here as establishment documentation, includes the reports and documents which are required to be generated in order to establish a laboratory which complies with the guide.

The second group, referred to here as periodic reports, are generated during scheduled audits and maintenance.

The third group, referred to here as event reports, are generated coincident to a specific occurrence.

The fourth group, referred to here as routine reports, which must be accomplished in the process of instrument calibration and material sampling in order to document the tests performed were in accordance with applicable procedures and governing documents, and are traceable to a primary standard having “the highest metrological qualities.”

Each group will be covered to provide the reader with a rough checklist of the establishment, periodic and routine documentation needed to show compliance with the Guide. If not otherwise annotated, any section mentioned refers to ISO Guide 25. Refer to the Cross-reference table for location with ISO/DIS 17025 or ANSI/NCLS Z540.

Establishment Documentation

The establishment documents group includes the reports and documents which are required in order to establish a laboratory which complies with the guide. Essentially, these documents fulfill the requirements of organization and management and exist in the form of a Quality Manual, a laboratory organizational chart and laboratory procedures which are specified throughout either Guide 25 or ISO/DIS 17025.

Characteristically, these documents are written once and used until superceded. They are typically reviewed, and revised if necessary, during annual audits prescribed by Guide 25.

The Quality Manual shall contain:

- Mission statement
- Purpose of the document
- Applicability
- Commitment to quality
- Templates for or references to laboratory procedures and documents.
- Definition of individual roles and responsibilities and job descriptions. (section 2.1 and 3.1.4)

The organizational chart(s) shall show the individual working and management relationships of all personnel within the lab as well as outside affiliations which may influence the lab's management.

Guide 25 specifies policies and procedures be promulgated or referenced on the following subjects but not limited to these subjects:

- All tests and calibrations carried out by the lab to include the use and operation of all relevant equipment and handling of test items. (section 3.3.1) Note that it is specified that if adequate externally available documentation is available, it need not be recreated as an internal procedure.
- Ensuring the protection of client confidential information and proprietary rights. (section 2.2.4c)
- Preventing activities, which might diminish confidence in the competence, impartiality, judgement, or operational integrity of the lab. (section 2.2.4d)
- Control and update of documents and information which forms part of quality documentation including procedures for changing computerized documents. (section 2.3)
- Selecting services and supplies which affect the quality of tests or calibrations. (section 2.6)
- Resolution of client feedback. (section 2.7)
- Performance of work which does not conform to lab procedures or client requirements. (section 2.8)
- Corrective action for non-conforming work. (section 2.9)
- Handling of quality and technical records including the handling of automated records. (section 2.11)
- If appropriate, material sampling procedures. (section 2.11.2.1)
- Identifying and fulfilling training needs. (section 3.1.2)
- Checking the lab environment does not adversely affect the performance of sampling. (section 3.2.2)
- Estimation of measurement uncertainty. (section 3.3.5)
- Calculation of best measurement capability. (section 3.3.6.1)

- Safe handling of measurement equipment. (section 3.4.13)
- Calibration and verification of laboratory equipment and reference standards. (section 3.5.1, section 3.5.3.1)
- Sampling of substances, matrices, materials or products if applicable. (section 3.6.1)
- Safe handling of test or calibration items. (section 3.7.1, section 3.7.4)

Externally produced procedures are specifically allowed provided they can be adequately applied for use within the lab.

Although the establishment documentation is commonly maintained in hard copy, there is no prohibition of maintaining such records electronically. The "Document and Information Control" section of Guide 25 (section 2.3) provides guidance on the format of internally produced documents.

Care should be taken to maintain a revision history for all documents regardless of the media. A list identifying the current revision status of documents in the quality management system must be readily available to all personnel who may use those documents.

Changes in ISO/DIS 17025

ISO/DIS 17025 handles "Organization and Management" and "Quality System" in two separate sections (4.1 and 4.2). This is similar to the treatment by Z540.

Periodic Reports

As mentioned above, the periodic reports are generated during scheduled audits and maintenance, or coincident to a specific, relatively infrequent occurrence.

Audits and systematic reviews:

The following periodic audits and systematic reviews must be conducted. An audit and systematic review schedule must be maintained, and each audit or review must be documented with a record of the findings and any corrective actions taken.

- Periodic audits are required on an annual cycle. These audits may be performed in discreet stages, but should encompass the whole quality test program annually. (section 2.12)
- Management reviews of the entire program must also be conducted annually. (section 2.13)
- Periodic internal monitor of lab tests or calibrations. (section 3.8)
- All operational procedures shall be systematically reviewed at regular intervals. (section 2.10)
- Documents are periodically reviewed to ensure continuing suitability and compliance with applicable requirements. This and the above item might be incorporated into a scheduled audit. (section 2.3.2.2)

Event related

The following records and documents must be maintained and updated as required by the occurrence of a given event.

- For each technical person in the lab, a list of educational, professional and technical qualifications attained and training requirements still needed. It would also be appropriate to list those tests and procedures which the individual is authorized by the lab to perform. (section 3.1)
- Any changes to operational procedures. (section 2.9)
- Records of main suppliers from whom it obtains services and supplies required for tests or calibrations. This will include any due diligence the lab has undertaken to insure the supplier can meet the quality requirements of the lab. (section 2.6.4)
- Each request, tender or contract must be reviewed. Although the request, tender or contract may be written or verbal, the record is maintained of the "review" of the contract and how the lab's resources may be employed to meet the requirements. (section 2.4.2)
- Asset handling information for laboratory equipment used in the performance of test or calibration. (section 3.7.2)
- Calibration and verification status of laboratory equipment used in the performance of test or calibration. (section 3.4.8)
- Client acceptance of subcontracted work. (section 2.5.1)
- Register of all subcontractors that it uses for tests or calibrations along with an assessment of each. (section 2.5.3)
- Changes to documents shall be annotated within the changed document where appropriate. (section 2.3)
- Records of all client complaints and of the investigations and corrective actions taken by the laboratory. (section 2.7.2)
- Methods not covered by standard specifications must be defined, written, validated and documented. (section 3.3.3)
- Validation of methods used in the laboratory. (3.3.4)
- Validation of automated equipment used during test or calibration. (section 3.3.7.2) Note that for purchased software, the manufacturer's validation statement may be used. This applies only if the software is used for the functions for which it was designed.
- Update of correction factors used in calibration procedures. (section 3.4.12)

Asset Information:

Records shall be maintained of each item of equipment significant to the tests or calibrations performed. The information required to be in each record is provided in section 3.4.6.

Event Related (optional)

The following is a list of events for which specific direction to maintain records is not made, but for which it may be prudent to maintain records in order to demonstrate compliance with Guide 25. Each lab should evaluate these to determine the prudence of maintaining such records.

- Systematic client positive and negative feedback. (section 2.7.2)
- Incidence of non-conforming work, facts found, short and long term corrective actions taken. (section 2.8)

- For any corrective action taken correct an identified problem, the root cause should be noted and there should, where appropriate, be a monitoring event to ensure the lab has been effective in overcoming the problem identified. (section 2.9.2, section 2.9.3, section 2.9.4)
- When equipment goes outside of the direct control of the laboratory for a period, or any time checks are needed to maintain confidence in the calibration/verification status of the equipment, confidence checks should be conducted. (section 3.4.9, section 3.4.11, section 3.5.3.3)

Changes in ISO/DIS 17025

ISO/DIS 17025 section 4.4.2 relaxes the wording of Guide 25 section 2.5.1 requiring that clients be notified of the intended use of a subcontractor. The client must still be advised of the use of subcontractors, but it is now recommended, not required, that the notification be in writing.

Routine Reports

As used here, this group is synonymous with reporting test and calibration results. "The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods." The requirements for reporting the results are presented in contiguous space in Guide 25 section 3.9, so they will not be reproduced here.

Guide 25 specifies requirements for test reports and calibration reports, the distinction between them being whether the quality procedure being performed for the client is a test, the validation of an existing presumed condition, or a calibration, the verification of a measurement instruments ability to meet specification.

The overlapping and non-overlapping requirements for each report are clearly segregated within the Guide, and the laboratory should take care to insure they are meeting the requirements for the appropriate report to avoid inefficiency.

Some items of note:

The requirements for the reports have been specified for the purpose of ensuring the competency of the laboratory and the traceability of the test or calibration. To this end, two "rules of thumb" which might be applied are:

> "Does the test report or calibration certificate provide enough information to recreate the test with the personnel, equipment, standards, methods, environmental conditions, and other conditions relevant to the results of the test?"
>
> "Does the test report or calibration certificate contain or provide reference to all of the relevant test points and uncertainties used in determining the overall test result?"

While these "rules of thumb" are not specifically the purpose of the routine reports, compliance with these precept for repeatability provides a common sense litmus test for the completeness of the report information.

Changes in ISO/DIS 17025

ISO Guide 25 section 3.9.2.5 notes discussed the extension of the UUT measured value being extended by the measurement uncertainty as the specific value which must fall within tolerance in order to prove compliance. Stipulation of this practice, commonly referred to as "guardbanding," has been somewhat relaxed in the wording of ISO/DIS 17025 section 5.10.4.2. This will allow for the use of different methods of considering the measurement uncertainty until an industry consensus can be reached.

ISO/DIS 17025 section 5.10.3.1.h offers an additional requirement which will probably be of small impact. This being that "additional information required by specific branches" be included in the test report. The term "branches" is somewhat ambiguous in the current wording. A safe assumption would be that this would include quality certifying agencies and clients.

ISO/DIS 17025 section 5.10.4.2 note also specifies that for the case of instrument adjustment or repair, the calibration results before the adjustment, often referred to as "as-found data," shall be reported if available.

Cross-referencing table for those sections pertaining to required documentation.

ISO Guide 25	ISO/DIS 17025	ANSI/NCSL Z540
2.1	4.1 & 4.2	4 & 5
2.2.4.c	4.1.4.c	4.2.c
2.2.4.d	4.1.4.d	4.2.b
2.3	4.3	
2.3.2.2	4.5.2.2	
2.4.2	4.4.2	
2.5.1	4.5.1	14.1
2.5.3	4.55	14.2
2.6	4.6	10.8 & 15
2.6.4	4.6.5	15.3
2.7	4.7 & 4.8	16
2.7.2	4.8	16.1
2.8	4.9	
2.9	4.10	5.5
2.9.2	4.10.2	
2.9.3	4.10.3	
2.9.4	4.10.4	
2.10	4.11	10.1
2.11	4.12	10
2.11.2.1	4.12.2.1	10.7
2.12	4.13	5.3
2.13	4.14	5.4
3.1	5.2	6
3.1.2	5.2.2	6.2
3.1.4	5.2.4	6.2
3.1.5	5.2.5	6.3
3.2.2	5.3	7
3.3.1	5.4.1	10.1 & 10.2
3.3.3	5.4.4	10.3
3.3.4	5.4.5	10.4
3.3.5	5.4.7	
3.3.6.1	5.4.6	
3.3.7.2	5.4.8	10.7
3.4	5.5	8
3.4.6	5.5.5	8.4
3.4.8	5.5.9	8.4
3.4.9	5.5.10	
3.4.11	5.5.12	9.6
3.4.12	5.5.13	
3.4.13	5.5.6	8.2
3.5.1	5.6.1	9.1
3.5.3.1	5.6.2	9.2
3.5.3.3	5.5.12	9.6
3.6.1	5.7.1	10.5
3.7.1	5.8.1	11
3.7.2	5.8.2	11.1
3.7.4	5.8.4	11.3
3.9	5.10	13
3.9.1	5.10.1	13.1
3.9.2.4	5.10.4	13.2
3.9.2.5	5.10.5	13

Conclusion

The purpose of this paper was to compile a compact list of the documentation requirements of ISO Guide 25 with a secondary goal of examining the replacement standard ISO/DIS 17025. The primary purpose has been met, and few requirements will surprise the reader.

The review of ISO/DIS 17025 found few changes which will impact the laboratory which already complies with Guide 25. As ISO/DIS 17025 replaces a Guide with a standard, some of its provisions regarding documentation have actually been relaxed in order to encompass reporting practices in areas where a consensus has yet to be reached.

It is hoped that this paper will be of use to a laboratory reviewing its own documentation for completeness.

Bibliography

ISO/IEC Guide 25, International Standards Organization, August 1996.

ISO/DIS 17025, International Standards Organization, March 1998.

Calibration Data Management: Collecting and Reporting Quality Information, Nicholas Mason, Paper presented at NCSL 96.

ANSI/NCSL Z540 – 1994, National Conference Of Standards Laboratories, July 27, 1994.

Biography

Patrick Kershaw graduated with an Aerospace Engineering degree from the University of Southern California in 1984. He spent eight years in the U.S. Navy working as a Nuclear Engineer and Submarine Warfare Officer while pursuing post-graduate studies in Nuclear Engineering and Software Engineering. Since leaving the service in 1991, he has pursued a career in Software Engineering attaining certification in Software Test and C++ Programming. Patrick is currently a Software Engineer in the Traditional Calibration Group at Fluke Corporation. His primary development focus has been in MET/CAL Metrology Software.